REMARKS

Claims 1-15 are all the claims pending in the application. Claims 7, 8, and 10-15 have been withdrawn from consideration. New claims 16-20 are directed to methods of administering the compound of formula 3. Applicants respectfully request that the claims be examined with claims 1-6 and 9 as the inventions are not independent and distinct.

I. Formal Matters

Applicants note that the Examiner did not return an initialed copy of the PTO 1449 Form filed with the Information Disclosure Statement on July 2, 2001. In view thereof Applicants formally request that an initialed copy be returned for our records.

II. Withdrawal of Finality of the Office Action dated July 31, 2001

Applicants thank the Examiner for the Notice dated November 20, 2001, indicating that the finality of the Office Action dated July 31, 2001, has been withdrawn in response to the Request to Withdraw Finality of the Office Action filed on October 30, 2001.

III. Claim Rejections Under 35 U.S.C. § 102

Claims 1-6 were rejected as allegedly being anticipated by Fahim (US 4,372,296) or Schinitsky et al (US 4,983,969).

The Examiner characterizes claims 1-6 as directed to a topical composition comprising a therapeutically effective amount of an ascorbic acid derivative and a zinc salt; or a zinc salt of said ascorbic acid derivative.

A. Fahim (US 4,372,296)

The Examiner asserts that Fahim teaches a topical composition required by claims 1-6, comprising zinc salt (e.g. zinc sulfate) and ascorbic acid. More specifically the Examiner asserts

that Fahim teaches an ascorbic acid composition that includes therapeutically effective amounts of both zinc salt (1-4%), and ascorbic acid (2-6%). According to the Examiner Fahim teaches that the disclosed composition provides a synergistic combination effect as an antimicrobial agent, especially effective in the treatment of acne when applied to the skin whether or not they are applied to the skin with ultrasonic vibrations.

It is the Examiner's position that even though the species of microorganisms (in claims 3-4) required in the claims is different from the species taught by the reference, it could be reasonably expected that the disclosed composition would inherently possess the ability to kill the organisms in the present claims as long as they contain the same therapeutically effective amounts disclosed in the instant specification (at page 15-17, 0.01-90% with ratio 1:0.1 to 1:10). Further the Examiner notes the recitation of intended use in the claims is not given patentable weight where there is no structural difference between the claims and the prior art.

Applicants respectfully traverse the Examiner's rejection. First, we note that the Examiner's statements that the disclosed composition would inherently possess the ability to kill the organisms in the present claims (3-4) as long as the same therapeutically effective amounts are used, is not a proper basis for a rejection based on inherency. It is not enough that a certain result or characteristic may occur or be present in the prior art to establish inherency. (See MPEP § 2112). It appears as if that the Examiner is referring to an obviousness argument that one of ordinary skill in the art may have been able to determine the proper therapeutically effective amounts or optimal range for killing the claimed microorganisms based upon the disclosure of Fahim et al. However, such a rationale is an improper basis for a rejection under 35 USC §102.

Further Applicants submit that it is disclosed in the present specification on page 11 that none of the known ascorbic acid derivatives exhibit an antibacterial and antienzymatic activity as high as the dermal agent of the present invention. This is also demonstrated in the Examples and Tables of the specification and confirmed by further experimental data provided in the Declaration under 37 C.F.R. § 1.132 submitted herewith. The method of treatment claims presented herein are believed to patentably distinguish over the cited reference for at least the same reason since the compound recited in the method is distinguishable.

B. Schinitsky et al (US 4,938,969)

Claims 1-6 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schnitsky et al. The Examiner states that Schnitsky et al teach a composition comprising zinc salt and ascorbic acid. It is the Examiner's position that all the critical claim elements required by the instant claims are met by the cited references based upon the same reasoning set forth above in regard to Fahim.

Applicants respectfully traverse the rejection and submit that it appears as if the Examiner has mischaracterized the disclosure of Schnitsky et al. The reference does not teach or disclose an antimicrobial effect or use for treatment of acne or acne related skin problems. Schnitsky et al disclose a composition for wrinkles or photo damaged skin and makes no mention of antibacterial properties. Therefore, Schnitsky et al do not anticipate the presently claimed invention.

IV. Rejections Under 35 U.S.C. § 103

Claim 9 was rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Sano et al in view of Fahim or Schnitsky et al. According to the Examiner, Sano et al teach a metal salt of ascorbic acid derivative such as magnesium L-ascorbic acid-2-phosphate and a process of making the composition. The Examiner asserts that Sano et al further teach that the disclosed composition has enhanced therapeutic effects and good stability and is effectively used in various skin disorders.

The Examiner states that Sano et al fail to exemplify a zinc salt of L-ascorbic acid phosphate as a final product, but that it would have been obvious to any ordinary skilled artisan to extend Sano's teaching to make zinc salt of L-ascorbic acid phosphate when it is taken in view of Fahim or Schnitsky et al because each of Fahim and Schnitsky et al teach the value of zinc salt in an ascorbic acid composition when it is applied in the treatment of skin conditions and emphasize that the combination of ascorbic acid and zinc salt enhances efficacy synergistically and improves stability as well.

The Examiner further asserts that even though Sano et al did not exemplify or was silent about a final product of zinc salt L-ascorbic acid-2-phosphate, one would formulate the zinc salt of L-ascorbic acid-2-phosphate without difficulty when based upon the disclosure of Sano et al's method or preparation.

Applicants respectfully traverse the Examiner's rejection on the basis that the Examiner has not made a *prima facie* showing of obviosuness. *Prima facie* obviousness requires that there must be a suggestion or motivation in the references or in the general knowledge of one of

ordinary skill in the art to modify the references or combine their teachings. Applicants submit that Sano et al only disclose a method for producing ascorbic acid derivatives. Sano et al do not disclose a method for producing a zinc salt of ascorbic acid phosphate and its inhibitory effect for treating acne. Thus, in this case there is no suggestion or motivation in Sano et al to make a compound of formula 3 as presently claimed or that such would be useful in compositions taught by Fahim or Schnitsky et al for the purpose of treating acne or diminishing wrinkles respectively. Additionally, neither Sano et al, Fahim, nor Schnitsky et al disclose the unexpectedly superior properties of the claimed L-ascorbic acid-2-phosphate zinc salt in regard to its effectiveness as a single agent antimicrobial for use in treating acne.

Further as admitted by the Examiner, Sano et al do not teach the final product of an ascorbic acid phosphate zinc salt. The Examiner suggests that one of ordinary skill in the art would nonetheless make the undisclosed ascorbic acid phosphate zinc salt based upon the disclosure of Sano et al and then substitute it for the combination products of ascorbic acid and zinc salts taught by each of Fahim et al and Schnitsky et al with a reasonable expectation of success of achieving Applicants' claimed single agent effective for the treatment of acne related disorders. Such rationale is improper hindsight reasoning since the claimed invention as a whole is not taught or suggested by the cited references and can only be reconstructed based upon Applicants' teachings in the specification.

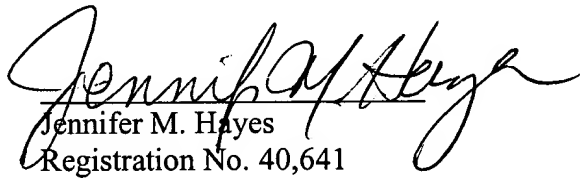
Accordingly Applicants respectfully request that the rejections be withdrawn.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 7, 8 and 10-15 are canceled.

The claims are amended as follows:

1. (Amended) A dermal agent according to claim 9, wherein said dermal agent is effective in the treatment or prevention of ~~for preventing or treating~~ acne~~, (A) compromising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~.

2. (Amended) ~~An antibacterial~~ A dermal agent according to claim 9, ~~(A) comprising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~ said dermal agent having activity as an antibacterial.

3. (Amended) A dermal agent according to claim 9, said dermal agent having an inhibitory effect on growth *of Propionibacterium,* ~~(A) comprising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~.

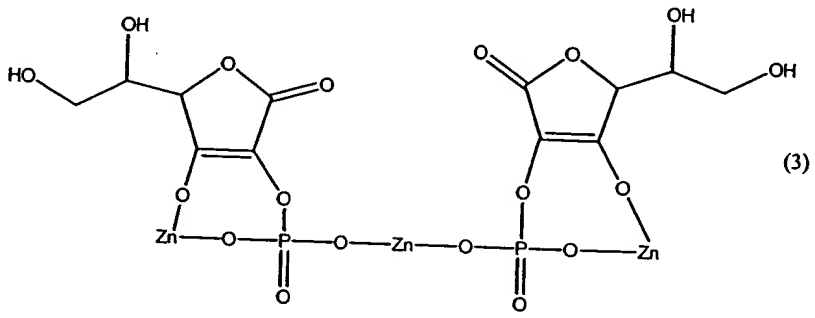
4. (Amended) A dermal agent according to claim 9, said dermal agent having an inhibitory effect on *Staphyloccocus,* ~~(A) comprising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~.

5. (Amended) A dermal agent according to claim 9, ~~comprising (A) comprising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~ said dermal agent having inhibitory activity against lipase derived from microorganisms.

6. (Amended) A dermal agent according to claim 9, ~~(A) comprising a therapeutically effective amount of an ascorbic acid derivative which liberates ascorbic acid in vivo or a salt thereof and a zinc salt compound or (B) comprising a therapeutically effective amount of a zinc salt of ascorbic acid derivative~~ said dermal agent having inhibitory activity against hyaluronidase derived from microorganisms.

9. (Amended) ~~The~~ A dermal agent ~~as claimed in any one of claims 1 to 6, wherein~~

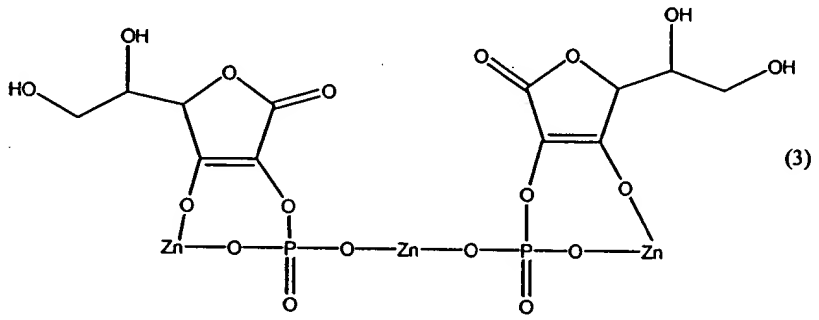
~~the zinc salt of an ascorbic acid derivative~~ comprising a therapeutically effective amount of a compound which liberates ascorbic acid in vivo ~~is ascorbic acid 2 phosphate zinc~~ salt represented by the following formula (3):



(3)

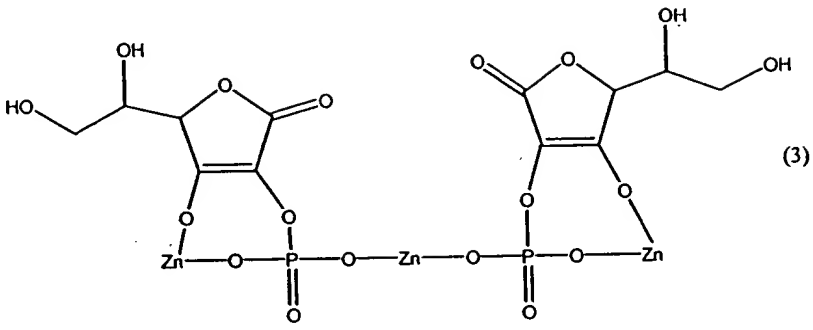
Claims 16-20 are added as new claims.

16. (New) A method for preventing or treating acne comprising administering a dermal agent comprising a therapeutically effective amount of a compound which liberates ascorbic acid in vivo represented by the following formula (3):



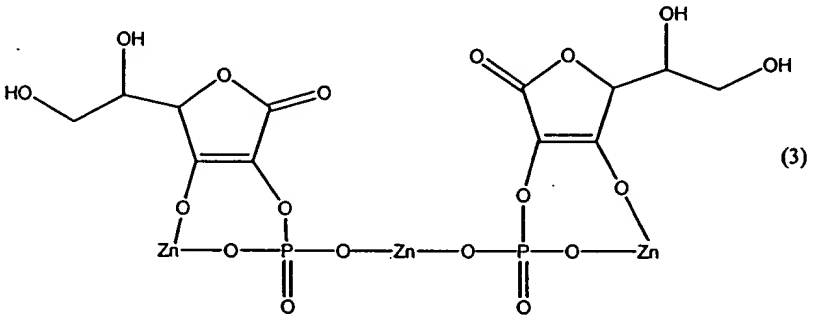
(3)

17. (New) A method for inhibiting the growth *of Propionibacterium*, comprising administering a dermal agent comprising a therapeutically effective amount of a compound which liberates ascorbic acid in vivo represented by the following formula (3):



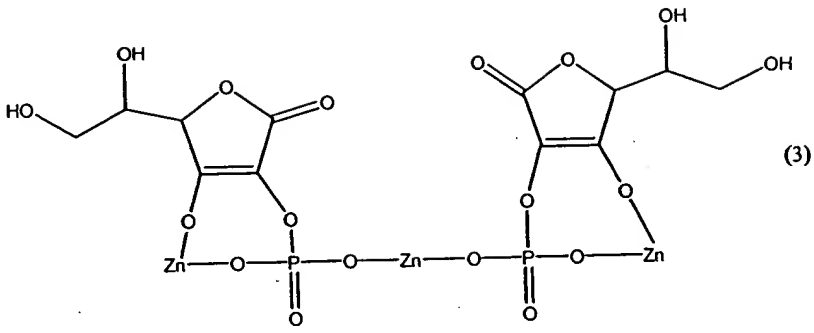
(3)

18. (New) A method for inhibiting the growth of *Staphylococcus*, comprising administering a dermal agent comprising a therapeutically effective amount of a compound which liberates ascorbic acid in vivo represented by the following formula (3):



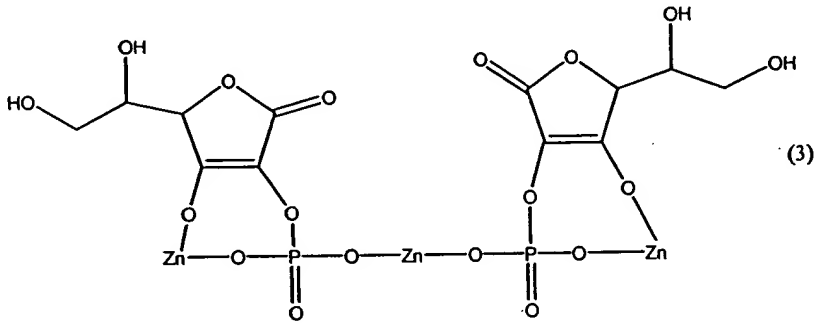
(3)

19. (New) A method for inhibiting the activity of lipase derived from microorganisms comprising administering a dermal comprising agent a therapeutically effective amount of a compound which liberates ascorbic acid in vivo represented by the following formula (3):



(3)

20. (New) A method for inhibiting the activity of hyaluronidase derived from microorganisms comprising administering a dermal agent comprising a therapeutically effective amount of a compound which liberates ascorbic acid in vivo represented by the following formula (3):



(3)